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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,684	01/30/2002	Charles L. Sawyers	30435.53USD3	4751

26941 7590 07/25/2003

MANDEL & ADRIANO  
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PASADENA, CA 91101

EXAMINER

TON, THAIAN N

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 07/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/062,684

Applicant(s)

SAWYERS ET AL.

Examiner

Thai-An N. Ton

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 21-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other:

### DETAILED ACTION

Applicants' Preliminary Amendments A [filed 1/30/02, Paper No. 2] and B [filed 3/27/02, Paper No. 3] have been entered. Claims 1-20 have been cancelled. Claims 21-34 have been added. Claims 21-34 are pending and under current examination.

Note that by Rule 1.126, the claims designated claims 2-15, in Paper No. 2, Preliminary Amendment B, have been re-numbered claims 21-34.

Note: This application has been filed as a divisional application of App. No. 09/567,202. However, as no restriction appears in the '202 Application, it is inappropriate to designate this application as a divisional application and the instant application would be considered a continuation of the '202 Application.

### *Priority*

The priority information in the first paragraph of the specification should be updated to reflect that U.S. App. No. 09/567,202 is now U.S. Pat. No. 6,365, 797 B1, U.S. App. No. 08/951,143 is now U.S. Pat. No. 6,107,540 and U.S. App. No. 08/732,676 is abandoned.

### *Oath/Declaration*

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because it lists 08/732,676 as a U.S. provisional Application. This case is a non-provisional case.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21-23, 27, 28, 30-33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-7 and 9 of U.S. Patent No. 6,365,797 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to methods of simulating the progression of human prostate cancer from

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primary tumor formation to micrometastasis or macrometastasis in an animal model. The instant claims are drawn to methods for simulating progression of human prostate cancer from primary tumor formation to micrometastasis or macrometastasis in an animal model and methods of simulating the progression of osteoblastic bone metastasis of human prostate cancer by use of a mouse model. In further embodiments, the claims are directed to the detection of the cancer cells in the peripheral blood of the mouse, and an intraprostatic human prostate cancer xenograft in a SCID mouse. The '797 claims are directed to methods of simulating the progression of human prostate cancer from primary tumor formation to micrometastasis using a human prostate cancer mouse model, methods of simulating the progression of human prostate cancer from primary tumor formation to micrometastasis using a human prostate cancer mouse model. The instant claims differ from the '797 claims in that some embodiments of the instant claims are broader in scope, see, for example, claim 22, which provides a step of detecting prostate cancer cells external to the implant site, whereas the '797 claims teach detection of the xenograft tumor in the peripheral blood of the mouse model [see claim 6, of the '797 claims, for example]. However, the instant claims are made obvious by the '797 claims, as both sets of claims are directed to the same methods.

Claims 21-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 7-10 of

U.S. Patent No. 6,107,540. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to methods of simulating the progression of human prostate cancer from primary tumor formation to micrometastasis in an animal model, and methods of simulating the progression of osteoblastic bone metastasis of human prostate cancer in a mouse model. The instant claims are directed to methods for simulating progression of human prostate cancer from primary tumor formation to micrometastasis or macrometastasis in an animal model and methods of simulating the progression of osteoblastic bone metastasis of human prostate cancer by use of a mouse model. In further embodiments, the claims are directed to the detection of the cancer cells in the peripheral blood of the mouse, and an intraprostatic human prostate cancer xenograft in a SCID mouse. The '540 claims are directed to methods of simulating the progression of human prostate cancer from primary tumor formation to micrometastasis (claims 1-3), methods for simulating the progression of osteoblastic bone metastasis of human prostate cancer in a mouse model (claim 4), and chimeric mouse models of human prostate cancer (claims 7-10). As both sets of claims are directed to methods of simulating progression of human prostate cancer utilizing the same mouse model, the instant claims are made obvious by the '540 claims.

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*Conclusion*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thái-An N. Ton whose telephone number is (703) 305-1019. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the examiner be unavailable, inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to William Phillips, Patent Analyst, at (703) 305-3482. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

TNT  
Thái-An N. Ton  
Patent Examiner  
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